Ref.: Patent Application No. 10/055,811
in the name of Clarbruno Vedruccio,
filed in the USPTO on 01/23/2002
(previously filed under the PCT on 07/26/2000 as International Application No. PCT/IT2000/000316)

AFFIDAVIT/DECLARATION TRAVERSING GROUNDS OF REJECTION

I, Andrea Tubaro, an Italian citizen residing at Via Val Pellice 53 – 00141 Rome, Italy, declare:

That I graduated in Medicine and Surgery at "La Sapienza" University of Rome with a degree of 110 cum laude in 1983.

That I did my postgraduate training in Urology at "La Sapienza" University of Rome between October 1983 and October 1988.

That I have been employed by L'Aquila University as Assistant Professor in Urology in 1988, since 2001 I have been employed by "La Sapienza" University of Rome as Associate Professor of Urology.

That I am not interested in the above application as an inventor, an employee of the assignee, etc.

That I have read and understood the specification of the above application.

That in order to prove that the TRIMprob device has a significant accuracy in the diagnosis of prostate cancer, I conducted the following studies:

- In a first study on 211 patients at risk of prostate cancer and undergoing prostate biopsy, TRIMprob test was performed blind of the patients status. Diagnostic accuracy of the TRIMprob was found to outperform any other diagnostic parameter including prostate specific antigen. The following diagnostic accuracy was observed for the TRIMprob: sensitivity: 95.4%, specificity 42.7%, positive predictive value: 63.6%, negative predictive value: 89.8%. Results of this study were published in European Urology, 2005;47:29-37.
- In a second study, 111 consecutive patients at risk for prostate cancer and schedule for prostate biopsy were blindly evaluated with the TRIMprob device before biopsy was performed. Analysis of diagnostic accuracy resulted in a sensitivity of 84% and a specificity of 63%. Positive and negative predictive values were 60% and 87%, respectively for a total accuracy of 72%. Results of this study were presented at the 2006 annual meeting of the European Association of Urology and the relative manuscript has been submitted for publication.
- In a third study, 15 male nude mice were injected with prostate cancer cells and 15 female nude mice were injected with a breast cancer cells. All mice were evaluated at baseline and following 1, 2 and 3 weeks from tumour implant. Results of the study showed a significant decrease of signal intensity at 465 MHz in tumour bearing mice compared to controls confirming the diagnostic capacity of the TRIMprob device in prostate and breast cancer models. Results of this study will be presented at the 2006 annual meeting of the Society of Academic European urologists (Amsterdam, December 8-10).

The above studies have demonstrated that prostate cancer can be detected by TRIMprob, using the frequencies subject of the above application (page 5, line 12).

From the above result, I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such wilful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 2 December 2006

Andrea Tubaro